K063490
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510(k) Premarket Notification
Spacelabs Medical, Inc.
Full Disclosure System, Model 91810
Summary of Safety and Effectiveness

MAR 15 2007

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Subject:	510(k) Summary of Safety and Effectiveness Information for the Spacelabs Medical Full Disclosure System, Model 91810
Submitter:	Spacelabs Medical, Inc. 5150 220th Ave SE Issaquah, WA 98029-6834 David J. Geraghty Phone: 1 425 657 7200 Fax: 1 425 657 7207 david.geraghty@slmd.com
Establishment Registration Number:	3023361
Proprietary Name:	Spacelabs Medical Full Disclosure System, Model 91810
Common Name	Full Disclosure System
Classification:	Programmable Diagnostic Computer, Product Code 74 DQK; 21CFR 870.1425. Class II
Performance Standard:	To the best of Spacelabs Medical, Inc.'s knowledge, performance standards have not been promulgated by FDA for this device.

Device Description:

The Spacelabs Medical Full Disclosure System (FD), model 91810, is a software application intended to be installed on an Off-The-Shelf (OTS) computer system utilizing a Microsoft operating system. The primary purpose of the FD system is to review, up to 72 hours of monitored patients' historical physiological waveform and alarm event information. The system also provides for a Retrospective Analysis of the stored ECG waveform data.

The Full Disclosure system is a software application that provides full-disclosure functionality for Spacelabs Medical bedside monitors. Depending on options purchased, a maximum of 72 hours of patient waveform history can be viewed for patients connected to the monitoring network. The system supports the following waveform channels: ECG Primary and secondary, Arterial pressure, Pulmonary artery pressure, Central venous pressure, Right atrial pressure, Intracranial pressure, Left atrial pressure, General pressure, Umbilical artery pressure, Pulse oximetry, Umbilical venous pressure, Adult or neonatal ventilator Flexport, Carbon dioxide / multigas Flexport or module, Sp02/ET02 Flexport and Respiration.

The Full Disclosure application allows the user to view and print the full array of waveform information collected from Spacelabs Medical bedside monitors connected to the Spacelabs Medical patient monitoring network. The Alarm events, 12 Lead Reports and waveform information is available to the user for up to 72 hours after the information is stored in the network's database.

In addition, the system incorporates a shape-based, Retrospective Algorithm that may be applied to the ECG waveform data, if desired. This Retrospective Algorithm can identify clinically significant ECG events and make them available for viewing and printing. When ECG analysis is performed, the results are stored locally, not in the database. Preference information, such as display and report options, is saved on the local machine, not in the database.

Intended Use:

The Spacelabs Medical Full Disclosure System is indicated for use in clinical situations where there is a need for review of physiological waveform information and alarm events up to 72 hours after the fact. The Full Disclosure System is also indicated in those situations where a retrospective analysis of monitoring patients' ECG waveform data, that can be annotated and edited, is desired

The intended use of the Spacelabs Medical Full Disclosure System is to interface with the Spacelabs monitoring network in order to provide the user with a means of recalling waveform information and retrospectively analyzing up to 72 hours of monitoring patient's most recent ECG waveform data.

Test Discussion: The Spacelabs Medical Full Disclosure System, Model 91810 and the Spacelabs Medical ECG analysis system, model 91810, K962930 are substantially equivalent in design concepts, technologies and materials. The Full Disclosure System was validated through rigorous testing that, in part, support the compliance of the software to the Standards mentioned in Section 9 of this submission. Additionally, the Full Disclosure software was developed following a robust software development process and was fully specified and validated. The test program verified that data available to the Full Disclosure System could be accurately recalled and that the Retrospective Analysis performed as expected.

Test Conclusion: The Spacelabs Medical Full Disclosure System, Model 91810, is substantially equivalent to its predicate devices in design concepts, technologies and materials. Testing demonstrates that Full Disclosure System is as safe and effective as the Spacelabs Medical ECG Analysis System, K962930.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2007

Spacelabs Medical
Mr. David Geraghty
5150 220th Ave SE
Issaquah, WA 98029-6834

Re: K063490
Trade Name: Spacelabs Medical Full Disclosure System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: February 27, 2007
Received: March 1, 2007

Dear Mr. Geraghty,

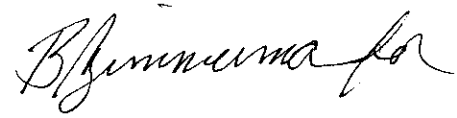
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K063490

Device Name: **Spacelabs Medical Full Disclosure System, Model 91810**

Indications for Use:

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Prescription Use **XX**	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063490